K042523

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

MAR 1 8 2005

Summary

1.0 Description

The Resection Pump 2228 is used in combination with a large diameter resectoscope to suction off tissue chips by a short pulse vacuum after the removal with a high-frequency electrode. The complete procedure is done under endoscopic view and continuous flow conditions.

2.0 Intended Use

The Resection Pump 2228 with Resectoscope 8659.xxx is used for endoscopically controlled tissue chip resection and removal of intrauterine polyps, intrauterine myoma or prostate adenomas via suction channel under continuous flow conditions following resection using a high- frequency electrode with a resectoscope.

3.0 Technological Characteristics

The airflow of the control tube is interrupted when the grip of the working element is in the end position and the tissue is cut. This results in a change in pressure which triggers the resection pump to open the tube clamp valve for a short period of time. This generates a brief vacuum pressure via the secretion trap and the tissue chip is sucked off and collected in the chip fluid trap.

The resection pump 2228 is software controlled. Key functions and components are automatically monitored to ensure safe operation. If there is a fault, a message is shown on the LCD display in conjunction with an acoustic signal.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices and the new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k)-devices sold by Richard Wolf and FemRx.

5.0 Performance Data

The resection pump 2228 is designed to meet the standards IEC601-1/ UL2601-1.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

Revised 03/08/05

By: Robert L Casarsa Date: Mar 8, 05

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2005

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
VERNON HILLS IL 60061-3110

Re: K042523
Trade/Device Name: Resection Pump and Resectoscope for Chip Aspiration
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: FJL
Regulation Number: 21 CFR §876.4370
Regulation Name: Gastroenterology-urology evacuator
Product Code: KQT
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Product Code: HIH
Regulatory Class: II
Dated: March 8, 2005
Received: March 9, 2005

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 Indications for Use

510(k) Number (if known): K042523

Device Name: Resection Pump and Resectoscope for Chip Aspiration

Indications For Use: The Resection Pump 2228 with Resectoscope 8659.xxx is used for endoscopically controlled tissue chip resection and removal of intrauterine polyps, intrauterine myomas or prostate adenomas via suction channel under continuous flow conditions following resection using a high-frequency electrode with a resectoscope.

Prescription Use ___✓___ AND/OR Over-The Counter _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042523